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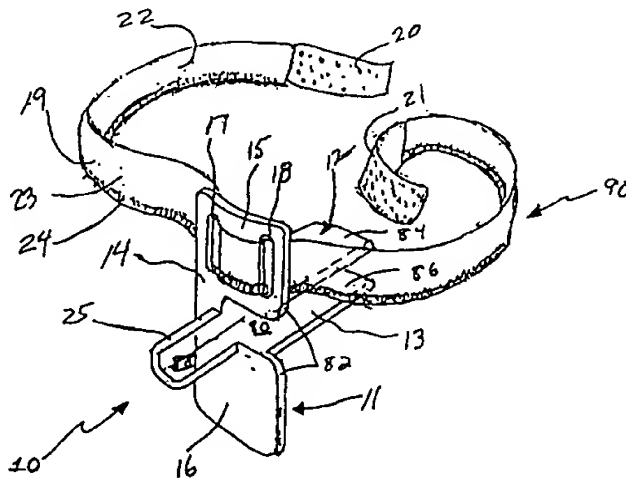
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US97/10049 (22) International Filing Date: 17 June 1997 (17.06.97) (30) Priority Data: 60/022,872 17 June 1996 (17.06.96) US Not furnished 13 June 1997 (13.06.97) US (71) Applicant: DALE MEDICAL PRODUCTS [US/US]; 7 Cross Street, P.O. Box 1556, Plainville, MA 02762 (US). (72) Inventor: RUSSO, Ronald, D.; 8 Candleberry Road, Barrington, RI 02806 (US). (74) Agent: MCLANE, Jodi-Ann; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: MEDICAL TUBE HOLDER AND BITE BLOCK**(57) Abstract**

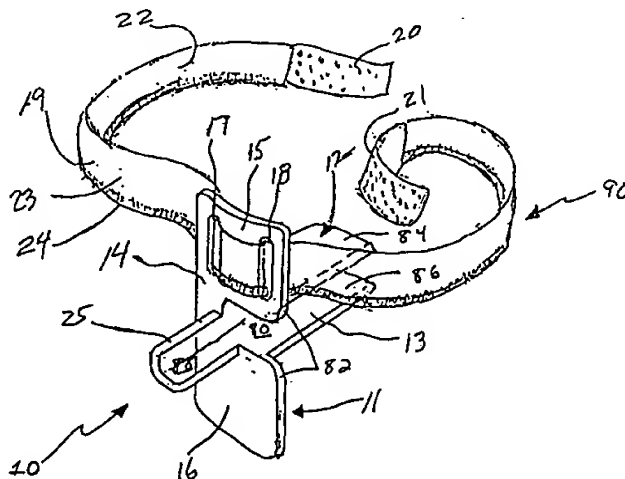
A medical tube holder (10) for securing a medical tube (31) in position within a patient's mouth is disclosed. The medical tube holder (10) includes a flange (14) which engages only a central portion of a patient's mouth during use, and a guard member (12) which is inserted into the mouth of the patient and which extends from the flange (14). Access to the side of the mouth of the patient is unobstructed by the use of the medical tube holder (10), as neither the flange (14) nor the guard member (12) contacts the side of the mouth, or adjacent area, of the patient's face. The flange (14) includes an upper portion (15) which is engageable with the upper lip (72) of the patient's mouth and may also include a lower portion (16) which is engageable with the lower lip (76) of the patient's mouth. The flange (14) provides support for the medical tube (31) and helps stabilize the medical tube holder (10) during use. The guard member (12) is configured to fit into the mouth of the patient and may provide protection to the medical tube (31) inside the mouth, and may also be utilized to support the medical tube (31).



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(54) Title: MEDICAL TUBE HOLDER AND BITE BLOCK



(57) Abstract

A medical tube holder (10) for securing a medical tube (31) in position within a patient's mouth is disclosed. The medical tube holder (10) includes a flange (14) which engages only a central portion of a patient's mouth during use, and a guard member (12) which is inserted into the mouth of the patient and which extends from the flange (14). Access to the side of the mouth of the patient is unobstructed by the use of the medical tube holder (10), as neither the flange (14) nor the guard member (12) contacts the side of the mouth, or adjacent area, of the patient's face. The flange (14) includes an upper portion (15) which is engageable with the upper lip (72) of the patient's mouth and may also include a lower portion (16) which is engageable with the lower lip (76) of the patient's mouth. The flange (14) provides support for the medical tube (31) and helps stabilize the medical tube holder (10) during use. The guard member (12) is configured to fit into the mouth of the patient and may provide protection to the medical tube (31) inside the mouth, and may also be utilized to support the medical tube (31).

MEDICAL TUBE HOLDER AND BITE BLOCK

Description

1. Cross-Reference to Related Application

5 This application claims priority to the present inventors' copending U.S. Provisional Application Serial No. 60/022872, entitled LONG TERM ENDOTRACHEAL TUBE BITE BLOCK AND HOLDER, filed June 17, 1996.

2. Technical Field

10 The present application relates to a medical tube holder, and more particularly to a medical tube holder including a bite block assembly.

3. Background of Related Art

15 Medical tubes or catheters are routinely used to orally intubate patients in order to provide a passageway for the transportation of air and other substances. One such tube utilized for intubation is an endotracheal tube which provides a critical airway for connection to a respirator machine or ventilator circuit for artificial respiration. Another type of tube utilized for intubation is a stomach or intestinal tube which is used to treat or to flush out the stomach of a patient. In some cases the medical tube will be used for less than a few days, such use being
20 generally termed short term use, but in some cases the tube will be utilized for several days upwards to a month, such use being generally termed long term use. Medical tubes used for intubation are typically made from semi-flexible, clear polyvinylchloride (PVC) and are available from a variety of suppliers. The tubes range in size, depending upon the use, with about 5-10 mm (inner diameter) for endotracheal tubes, and up to about 40 Fr (outer diameter)
25 for stomach/intestinal tubes being standard.

During oral intubation, a first end of the medical tube is inserted into the oral cavity of the patient and is guided to the desired internal location, for example the trachea or stomach, while the second end of the tube typically remains outside the oral cavity. When utilizing an endotracheal tube, the first end of the tube is inserted through the mouth of the patient and is
30 guided to within the patient's trachea. A pilot balloon, which is attached to the first end of the tube, is then inflated by an inflation tube which also extends through the patient's mouth and into the trachea. The second end of the tube remains outside the mouth of the patient and includes a

fitting which is attached to a respirator or ventilator circuit. The inflated balloon forms an internal seal within the trachea such that all administered respiration can flow out of the first end of the tube and into the patient's lung. When utilizing a stomach or intestinal tube, the first end of the tube is inserted through the mouth of the patient and is guided to within the patient's stomach, in order to provide a passageway to the stomach, for example to remove ingested substances. The second end of the tube remains outside the mouth of the patient and may be connected to a funnel or other device. In some cases the medical tube will be used for less than a few days, such use being generally termed short term use, but in some cases the tube will be utilized for several days upwards to a month, such use being generally termed long term use.

Because intubated medical tubes often provide a critical function, it is desirable that these tubes be held in place with little movement and that the passageway of the tube remains unobstructed. In the case of endotracheal tubes, the tube provides a critical airway for the patient and is often inserted for long term use. In order to secure endotracheal tubes, various devices have been designed. Cobbled up tongue depressors which are taped to the endotracheal tube, wrapped tape, straps, elastics, and endoscopic bite blocks have all been used to secure the tube in place. Various devices have also been developed which hold the tube in place while also preventing the patient from biting on the tube, especially for long term use. Molded bite block channels with outwardly extending side flanges to which straps are attached are well known in the art. Some devices utilize pull ties or flexible straps which lock to the tube, while others utilize a flat or curved frontal tab which is utilized with surgical tape secured to the tube. In the case of stomach/intestinal tubes, the use may be shorter term, but the patient is often uncooperative and combative, making it difficult to prevent the patient from biting on the tube, thereby obstructing the passage of narcotics, or the like, which may be pumped from the patient's stomach.

While helpful in aiding to secure medical tubes in place, conventional devices often utilize side flanges which contact the side of the mouth. Conventional devices are also traditionally used in conjunction with a fastener such as straps, foam or tape which engages the patient's lower cheeks. Such devices can produce skin break down and excoriation on the cheeks and face where these devices contact the skin, especially during long term use. In addition, because conventional devices are often secured at the side of the patient's mouth, the ability to access the tube is limited. Also, with a conventional device the amount of movement of the tube increases as the patient's moves his or her mouth, in that the side of the mouth likewise moves.

Known devices can also be difficult to apply due to their often complex construction and fastening mechanisms.

Thus, there is need for a simple, convenient and inexpensive medical tube holder and bite block for securing a medical tube in position within a patient's mouth, especially for long term patient use, while also protecting the tube from being crushed by the patient.

Summary

In accordance with the present invention, there is provided a medical tube holder for securing a medical tube in position within a patient's mouth. The medical tube holder includes a flange which engages only a central portion of a patient's mouth during use, and a guard member which is inserted into the mouth of the patient and which extends from the flange. Access to the side of the mouth of the patient is unobstructed by the use of the medical tube holder, as neither the flange nor the guard member contacts the side of the mouth, or adjacent area, of the patient's face. The flange includes an upper portion which is engageable with the upper lip of the patient's mouth, and may also include a lower portion which is engageable with the lower lip of the patient's mouth. The flange provides support for the medical tube and helps stabilize the medical tube holder during use. The guard member is configured to fit into the mouth of the patient and may provide protection to the medical tube inside the mouth, and may also be utilized to support the medical tube. In one embodiment, the guard member is a generally rectangular member having an opening along one end thereof. In another embodiment, the guard member includes a top plate which is supported by an intermediate bracket.

The medical tube holder may also include an attachment member supported by the flange for securing the medical tube holder to the patient. In one embodiment, the attachment member is a strap which is received within a slot formed in the upper portion of the flange. The strap may be adjustable and may be configured to wrap around the patient's head and lie adjacent the patient's cheekbones. The medical tube holder may further include a support bracket which extends forwardly from the flange, exterior to the mouth of the patient, in order to provide additional support to the medical tube.

It is therefore an object of the present invention to provide a medical tube holder which can be used as a combination bite block and tube holder to accept various size medical tubes, including, but not limited to, endotracheal as well as stomach/intestinal tubes.

Other objects of the present invention include providing a medical tube holder with one or more of the following features:

is lightweight and inexpensive, convenient to use, and can be rapidly setup;
can adapt to various patients, with one size for adults and one size for pediatrics;
5 can readily fit over the tube, after the tube is intubated, without dislodging the tube;
both supports the tube and prevents damage to the tube and to the fragile pilot balloon inflation tube, if utilized;

has minimal contact with the mouth, lips, and cheek areas of the patient's face to minimize skin damage;

10 permits readjustment of the tube without having to remove the bite block;
permits unobstructed access to both side areas of the mouth and lips;
cannot be aspirated or swallowed by the patient;
can be quickly and safely inserted around the tube in an emergency situation.

These and other features and benefits of the present invention will be more particularly
15 described in the following detailed description and drawings.

Brief Description of the Drawings

Figure 1 is a perspective view of one embodiment a medical tube holder, according to the present invention, including a strap with a Velcro™-style closure;

20 Figure 2 is a top view of the medical tube holder of Figure 1 without the associated strap;

Figure 3 is a front view of the medical tube holder of Figure 2;

Figure 4 is a cross sectional side view of the medical tube holder of Figure 3 taken along lines 4-4;

Figure 5 is a perspective view of the medical tube holder of Figure 1 ready to be attached
25 to an intubated patient;

Figure 6 is schematic of a patient intubated with an endotracheal tube including a pilot balloon inflation tube;

Figure 7 is a partial cross sectional view the medical tube holder of Figure 1 inserted over the endotracheal tube and pilot balloon inflation tube of Figure 6;

30 Figure 8 is a side cross sectional view of the medical tube holder of Figure 7 utilizing a piece of foam tape to secure the endotracheal tube and pilot balloon inflation tube to a support bracket of the tube holder;

Figure 9 is a front view in partial cross-section taken along line 8-8 of Figure 8;

Figure 10 is a front view of the medical tube holder of Figure 1 illustrating the contact area of the tube holder and unobstructed access to both sides of the lips, mouth, and oral cavity after being secured to the face of the patient;

5 Figure 11 is a front view of a second embodiment of the invention, using foam tape strips to secure the device to the upper lip and lower chin of the patient;

Figure 12 is a perspective view of a second embodiment of the medical tube holder of the present invention, including a strap with a Velcro™-style closure, where the device serves primarily as a tube holder only;

10 Figure 13 is a top view of the medical tube holder of Figure 13 without the associated strap;

Figure 14 is a front view of the medical tube holder of Figure 14;

Figure 15 is a cross-sectional view of the medical tube holder of Figure 15 taken along lines 15-15;

15 Figure 16 is a rear view of the medical tube holder of Figure 13;

Figure 17 is a front view of a third embodiment of the medical tube holder of the present invention, including an upper portion supporting a pair of extensions for added support in place of a lower portion; and

20 Figure 18 is a perspective view of a fourth embodiment of the medical tube holder of the present invention, having a guard member supported by a flange, without the use of a support bracket.

Detailed Description of the Preferred Embodiments

25 A medical tube holder 10 for securing and protecting a medical tube 31 used for oral intubation of a patient, for example an endotracheal tube, is illustrated in Figure 1. The medical tube holder 10 includes a housing 11 having a flange 14 which is configured and dimensioned to be supported by a central portion of a patient's mouth, and a bite block or guard member 12 extending from and supported by the flange 14. Flange 14 includes an upper portion 15 configured to rest against a central portion 70 of an upper lip 72 of the patient, and may also include a lower portion 16 configured to rest against a central portion 74 of a lower lip 76 of the patient, as shown in Figure 10. Flange 14 further includes an opening or slot 78 formed therein for receipt of medical tube 31 (Fig. 7), the opening preferably being aligned with a passageway

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80 extending through guard member 12. In the present embodiment, opening 78 extends through a side wall 82 of flange 14, so that the flange may be readily slid over medical tube 31, after the tube has been intubated. The flange may additionally be contoured in order to comfortably fit over the mouth of the patient and may be dimensioned to fit a majority of adults. In the present embodiment (see Fig. 3), the flange 14 has an overall length, "l", of about 3 inches, and a width, "w", of about 1 inch, although other dimensions and shapes are contemplated: generally the flange should be large enough to prevent the flange from inadvertently entering the mouth of the patient, even when opened wide, and not obstruct access to either side 43, 44 (Fig. 10) of the patient's mouth. Vertical flange 14 also supports horizontal guard member 12 which may be integrally molded therewith in an injection molding process, if desired.

A first embodiment of guard member 12 is illustrated in Figure 1. Guard member 12 provides protection for a first end of medical tube 31, which extends into the oral cavity of the patient, and may additionally provide support for the medical tube. If a pilot balloon 35 (Fig. 7) is provided, the guard member 12 may also provide protection and support for the inflation tube 33 connected to the pilot balloon. Guard member 12 extends rearwardly, i.e. proximally, from flange 14 toward the mouth of the patient and may include a longitudinal opening 13 extending along the length thereof. As shown in Figure 4, the guard member includes an exterior surface 84 and an interior surface 86, the interior surface preferably including a continuous floor 26, a ceiling 27 spaced from and opposed to the floor, and a sidewall 28 disposed between the floor and the ceiling, opposite opening 13. Guard member 12 may preferably be rectangular in shape and may be sized to comfortably fit within the oral cavity of a majority of patients, while also accommodating a majority of medical tubes used for intubation, the tubes being conventional tubes available from a variety of suppliers, as previously described. In the present embodiment, guard member 12 extends rearwardly from flange 14 about 1 1/8" and preferably accommodates medical tubes ranging in size from about 5-10 mm (inner diameter) for endotracheal tubes, and up to about 40 Fr (outer diameter) for stomach/intestinal tubes. Alternately, the guard member may be other shapes, such as cylindrical, and may be various sizes, for example, to fit infants and/or to receive other size medical tubes.

Medical tube holder 10 may also include a support bracket 25 supported by and extending in a forward direction, i.e. distally, from flange 14. Support bracket 25 is constructed and arranged to provide support for a second end of the medical tube 31 which remains exterior to the oral cavity of the patient after intubation. Support bracket 25 preferably defines a channel

88 which is axially aligned with passageway 80 of guard member 12. In the embodiment of Figure 1, support bracket 25 has a generally "L" shape, defined by a vertical, or upward extending wall 29 and a horizontal, or lower extending wall 30. Walls 29 and 30 operate to cradle the exterior portion of tube 31 and may also cradle and protect the pilot balloon inflation tube 33, if one is provided. Support bracket 25 may be any of a variety of shapes and/or sizes, for example, "c" shaped, the bracket extending forward of flange 14 about 3/4" in the present embodiment.

As shown in Fig. 9, the inflation tube 33 may be positioned within channel 88, in the corner of bracket 25, between tube 31 and walls 29, 30. The corner portion of bracket 25 thereby forms a continuous trough or safety tract 89 into which the small bore (approximately 3 Fr) pilot balloon inflation tube can safely nest without being impacted by the patient's teeth, or otherwise damaged. This tract may extend outward over the entire length of the forward extending support bracket 25. The inflation tube 33 may, additionally, be cradled and protected by the guard member 12 in a substantially similar fashion. If desired, a pressure sensitive adhesive strip 38, may be wrapped around tube 31 and bracket 25 in order to firmly attach medical tube 31, and inflation tube 33 (if provided), to the bracket 25.

Strip 38 may preferably be a specially supplied, cross-linked polyethylene pressure sensitive foam tape which is soft, flexible, conformable, moisture resistant, and which can be double wrapped 42 over itself to firmly secure the tube 31 to bracket 25. One such non-irritating foam tape can be made from polyethylene foam and skin contact grade tape, or an equivalent tape which possesses most of the above properties. The tape may also be repositionable so that it can be removed and replaced if tube 31 needs to be repositioned within channel 88, without having to remove the device from the patient's mouth; additional foam tapes may be supplied for repositioning. Strip 38 may be dimensioned to wrap around various size tubes 31, and is about 1/32" thick, about 7/8" wide and 4" long, in the present embodiment. The strip may include a peel back lip 39, for peeling back pressure liner 40, to expose acrylic adhesive 41 disposed on one side thereof. Other sizes and types of tape may be used, as would be known to one of skill in the art.

Referring again to Figure 1, an attachment member 90, for example a flexible strap 19, may be utilized with medical tube holder 10 to secure the holder to the patient's face. Strap 19 may be disposed through one or more slots 17, 18 formed in upper portion 15 of flange 14 so that the strap engages the patient's upper lip, as well as the patient's face adjacent his left cheekbone

47 and right cheekbone 48. during use. It is desirable to place the strap adjacent cheekbones 47, 48 because the cheekbones can more readily support the compressive forces of the strap than the soft lower left and right cheek areas 45 and 46. respectively. Since there is no direct contact with the soft lower cheek areas 45, 46. these areas remain substantially free of skin damage which may otherwise result from many conventional devices. Strap 19 may be adjustable to fit a wide variety of patients and may be formed from a length of material folded over and sewn to form an inside surface 22 which contacts the patient's head during use, and an outside surface 23 which is opposite the inside surface.

Strap 19 may further include a fastener, for example Velcro™-style strips 20, 21 having hook-like protrusions, which may be attached at either end so that the strap can be releasably secured about the head of the patient. By securing one Velcro™-style strip 20 on a first end of the strap facing the inside surface 22 and securing the second Velcro™-style strip 21 on a second end of the strap facing the outside surface 23, the strips 20, 21 can be overlapped (i.e., with loops) to secure the strap in place. Alternately, strips 20, 21 may each face the inside surface 22, and strap 19 may be criss-crossed prior to securing strips 20, 21. In addition, strap 19 is preferably made of a soft pile material (i.e., with loops) along the length of both the inside and outside surfaces so that the hook Velcro™-style strips 20, 21 may be attached anywhere along the strap 19 during use, thereby making the strap infinitely adjustable along any portion of the strap. Using a soft pile material also allows the strap 19 and tube holder 10 to be adjusted by a health care professional, for example to the left or right, without disconnecting the Velcro™-style strips 20, 21. Adjustment may be desirable to relieve pressure applied to certain areas of the tongue or mouth, especially in a long term application. Strap 19 may alternately be made of any material suitable for contacting the skin of the patient and securing the tube holder, may be a single piece of material which is not folded over and sewn, and may include any number or style of fasteners for releasably securing the strap in place. In the present embodiment, strap 19 is about 24" long by 1" wide and the Velcro™-style strips are each about 2" long by 7/8" wide. In use, the strap is wrapped around the patient's face adjacent his/her left and right cheekbones 47, 48 and is secured in place by strips 20, 21. For some patients, such as head trauma patients, it may be desirable to secure the medical tube holder 10 in an alternate manner, without the use of strap 19.

Figure 11 illustrates an alternate manner for securing the medical tube holder 10 in place. As shown in Figure 11, horizontal adhesive strips 49 and 50 may be applied over the upper portion 15 and lower portion 16 of the flange 14 to attach the flange to the upper lip 72 and lower lip 76 (or chin), respectively. Because strap 19 is not being used, the upper portion 15 need not be provided with slots 17, 18. Adhesive strips 49, 50 may preferably be repositionable so that repositioning of the medical tube holder may be accomplished without replacement of the strips 49, 50. The strips 49, 50 may, additionally, be identical to adhesive strip 38 as previously described, so that there will be no confusion on the part of medical personnel as to which strip to use to wrap tube 31 and which tape to use to adhere the flange. Additional foam strips and alcohol wipes may be provided if removal of the tape and repositioning of the device is desired. Alternately, pressure sensitive adhesive may be applied directly to the inner surface of flange 14 which contacts the patient's face. Such adhesive may be an acrylic adhesive covered with a peel-back liner that can be removed to expose the adhesive prior to use. Once the adhesive is exposed, the flange 14 may then be positioned and secured in place by applying pressure to the outer surface of the flange.

Housing 11, including flange 14 and guard member 12, may preferably be injection molded as a unitary structure from a rigid thermoplastic, such as Phillips K-resin. Alternately, the housing may be made from other rigid or semi-rigid materials or a combination of materials, for example, polypropylene, polycarbonate, ABS, or high impact styrene. Depending upon the material used, the housing may be molded clear, naturally translucent, with a slight tint, or opaque, if desired. In addition, portions of the housing, such as flange 14, may be formed with a foam backing for added comfort.

The operation of medical tube holder 10 will now be described with reference to Figures 5-7. The medical tube holder 10 along with an associated attachment member, such as strap 19 or adhesive strips 49, 50, is removed from its packaging, which may be in the form of a ready to use kit that can be easily and conveniently set up by a health care professional. After the patient has been properly intubated, for example with an endotracheal tube as shown in Figure 6, the opening 13 of the guard member 12 is aligned with the portion of the tube 31 remaining outside the oral cavity of the patient, and with inflation tube 33, if provided. Usually at least 3" to 4" of the tube extends out of the patient's mouth. Once aligned, the holder 10 is slipped over the exterior portion of tube 31, such that the inflation tube 33 is captured in tract 89, between the endotracheal tube 31 and the support bracket 25. The housing 11 is then slid proximally, until

the guard member is inserted into the oral cavity of the patient and the upper and lower flanges rest comfortably against the central portion of the patient's mouth. Once in place, the device is secured by either wrapping the strap 19 about the patient's head and adjusting it, or by applying adhesive strips 49, 50, as described above. If desired, an adhesive strip 38 may be wrapped
5 around tube 31 and bracket 25 in order to better secure the tube 31 to the holder 10, also as described above. Prior to wrapping adhesive strip 38 around tube 31, it may be desirable to wipe the tube clean with an alcohol prep wipe to clean and prepare the tube for increased adhesion of the tape 38. Once in place, the tube holder 10 provides a lightweight yet secure device for protecting both the medical tube and any associated tube, such as the inflation tube, from being
10 damaged or crushed. If the medical tube is double wrapped with an adhesive strip of foam tape, the tube becomes very difficult to pull out of the patient's mouth because the tube is securely wedged against the walls of the support bracket. This is especially important for combative or disoriented patients who may try to pull on the tube.

The medical tube holder of the present invention provides protection and support for an
15 intubated tube while allowing unobstructed access to either side of the patient's oral cavity, where oral suctioning or cleaning may take place. Also, the lips of the patient are clearly visible so that color, texture, and appearance of the lips can be readily visualized by medical personnel to detect any difficulties in respiration. This is important because bluish tinged lips can indicate low oxygen intake such that the percentage of oxygen may have to be increased. In addition,
20 breakdown of the skin is minimized as no part of the medical tube holder contacts the side of the mouth, lower cheeks or adjacent area, of the patient's face.

Referring now to Figures 12-16 a second embodiment of the medical tube holder 10 is illustrated. Elements which are similar, or the same as, those previously described in the embodiment of Figure 1 are labeled with the same reference numeral, preceded by the number
25 "1". As shown in Figure 12, medical tube holder 110 includes a flange 114 having an upper portion 115 configured to rest against a central portion of an upper lip of the patient (not shown), and may also include a lower portion 116 configured to rest against a central portion of a lower lip of the patient (not shown). Tube holder 110 further includes a partial guard member 112 which is configured to be received within the oral cavity of the patient and which includes a plate
30 member 153. Partial guard member 112 may be used in place of the full guard member 12 for patients who do not require a full bite block feature, or for those patient's where direct access to all ports of the oral cavity, including the tongue and salivary glands, is desirable. Removal of the

full guard member 12 may be more comfortable for patients, especially if the patient is cooperative and may only need intubation for several days, in which case the primary need is to provide a support for the medical tube, and not necessarily protection of the tube. The partial guard member 112 includes only plate member 153, in the embodiment of Figure 12. The molded plastic housing structure may be weakened by use of a partial guard member, and an intermediate bracket 154 may be included to compensate for this effect, in order to keep upper portion 115 and lower portion 116 rigid and fixed in place. Plate member 153 is supported by the intermediate bracket 154 which is disposed between flange 114 and support bracket 125. Intermediate bracket 154 may be generally "c" shaped, thereby providing the additional benefit of a second tract 162 for placement and protection of the balloon inflation tube (Fig. 16).

Plate member 153 may additionally include a short, downward extending sidewall 128 (Fig. 15) which increases the structural integrity of the partial guard member 112. Sidewall 128 may include a slightly rolled outward flare 159 (Fig. 16), which provides a flat edge 160 onto which the patient's lower teeth can bottom out, while the patient's top teeth may rest at a point 157 (Fig. 15). Plate member 153 helps prevent upper portion 115 of flange 114 from being wedged upwards and further keeps the tube holder fixed within the patient's mouth, regardless of movement of the patient's lower jaw. The lower jaw can, therefore, be opened or closed as desired or needed, and the plate member 153 and the upper portion 115 will keep the tube holder 110 stable in the patient's mouth. The placement of the medical tube within the holder 110 after intubation is the same as for the embodiment of Figure 1, as described above. Taping the tube (not shown) to the support bracket 125, as described above, will provide additional support so that the tube remains locked and held in place.

A third embodiment of medical tube holder 10 is illustrated in Figure 17. Elements which are similar, or the same as, those previously described in the embodiment of Figure 1 are labeled with the same reference numeral, preceded by the number "2". As shown in Figure 17, medical tube holder 210 includes a flange 214 having an upper portion 215 configured to rest against a central portion 270 of an upper lip 272 of the patient. Flange 214 further includes side extensions 292, 294, which rest against the face of the patient, between the patient's nose and upper lip 272. In this embodiment, the side extensions 292, 294, provide additional support to tube holder 210, thereby replacing the lower portion 16, 116 of the flange described in the previous embodiments. Attachment of the tube holder may be accomplished by looping a strap (not shown) through slots 217, 218 or by utilizing adhesive strips 249 and 250, as previously

described. Guard member 212 extends into the mouth of the patient, as described above with respect to Figure 1. Likewise, a support bracket 225 may also be provided, as previously described. Medical tube holder 210 provides protection and support for an intubated tube (not shown) while providing increased access to the oral cavity of the patient.

5 A fourth embodiment of the medical tube holder 10 is illustrated in Figure 18. Elements which are similar, or the same as, those previously described in the embodiment of Figure 1 are labeled with the same reference numeral, preceded by the number "3". As shown in Figure 18, medical tube holder 310 includes a flange 314 having an upper portion 315 configured to rest against a central portion of an upper lip of the patient (not shown), and may also include a lower
10 portion 316 configured to rest against a central portion of a lower lip of the patient (not shown). Tube holder 310 further includes a guard member 312. Medical tube holder 310 is identical to the tube holder previously described with respect to Figure 1, except a support bracket 25 is not provided. Removal of the support bracket 25 may be desirable in certain situations, especially in short-term applications where use of a bite block may be desired, but which do not require
15 stabilization of the medical tube. For example, during evacuation of the stomach it may be desired to use guard member 312 to protect the tube if the patient is combative, but further stabilization of the tube during such a short-term procedure may not be required. If further stabilization of the tube is desired for the embodiment of Figure 18, the tube may be taped to flange 314. The adhesive strip wrapped around the tube and flange 314 may be the same style
20 strip as described above for taping the tube to support bracket 25. The placement of the medical tube within holder 310 after intubation is otherwise the same as for the previous embodiments.

The adult version of the medical tube holder described hereinabove will securely accept both endotracheal and stomach/intestinal, as well as other medical tubes, with or without a balloon and inflation tube. A pediatric version is also contemplated which would be a slightly
25 smaller, scaled down version, with dimensions reduced by about 50%.

It will be understood that various modifications may be made to the embodiments disclosed herein. For instance, the guard member may be square, semi-circular, round, or oblong, but preferably includes a side opening which may be positioned either right or left for insertion of the tube. Various flange styles having different contours, such as rounded or curved
30 upper and lower portions and/or sides may also be made without impacting the function of the device. Likewise, although the position, location and configuration of the support bracket is shown in the first embodiment, it likewise could vary in shape, location, and style without

departing from its intended use. For instance, the support bracket may be a "c" shape or an "I" shape. In addition, various types of straps may be used with the housing, such as ones made from elastic rubber, single ply Velcro™ pile, or foam-style Velcro™ material. As such, wide variations in style, shape and location of the various elements can be made without departing
5 from the scope of the invention. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments.

CLAIMS

1. A medical tube holder configured and arranged to be partially inserted into a mouth of a patient, comprising:

a flange having an upper portion engageable with an upper lip of the mouth along a central portion thereof and a lower portion engageable with a lower lip of the mouth along a central portion thereof; and

a guard member extending from said flange, said guard member configured and arranged for insertion into the mouth of the patient;

wherein said flange engages only a central portion of the mouth of the patient such that access to the mouth along a first and a second side thereof is unobstructed when said guard member is inserted into the mouth of the patient.

2. The medical tube holder according to claim 1, further comprising a support bracket extending outwardly from said flange, said support bracket being axially aligned and spaced from said guard member and further being configured and arranged to support a medical tube.

3. The medical tube holder according to claim 2, further comprising a fastener dimensioned to secure the medical tube to said support bracket.

4. The medical tube holder according to claim 3, wherein said fastener includes a length of tape dimensioned to wrap around the medical tube and support bracket.

5. The medical tube holder according to claim 1, further comprising an attachment member engageable with said upper portion of said flange, said attachment member being configured and arranged to engage the patient's face, adjacent a first and a second cheekbone.

6. The medical tube holder according to claim 5, wherein said attachment member includes a strap.

7. The medical tube holder according to claim 6, further comprising at least one slot disposed through said upper portion, said slot being dimensioned for receipt of said strap.

8. The medical tube holder according to claim 1, further comprising adhesive for attaching said upper portion of said flange to the patient's face.

9. The medical tube holder according to claim 1, wherein said flange is contoured.

10. The medical tube holder according to claim 1, wherein said guard member includes a floor, a ceiling spaced from and opposed to said floor, a sidewall disposed between said floor and said ceiling and a longitudinally extending opening disposed opposite said sidewall.

11. The medical tube holder according to claim 2, further comprising an intermediate bracket disposed between said guard member and said support bracket.

12. The medical tube holder according to claim 11, wherein said guard member includes a top plate supported by said intermediate bracket.

13. A medical tube holder configured and arranged to protect a medical tube received within an oral cavity circumscribed by a mouth of a patient, comprising:

a flange including an upper portion and a lower portion, said upper portion being engageable with an upper lip of the mouth and said lower portion being engageable with a lower lip of the mouth, said flange having a width; and

a guard member extending from said flange, said guard member being configured and arranged for insertion within the oral cavity of the patient;

wherein the width of said flange is dimensioned such that said medical tube holder, upon insertion of said guard member within the oral cavity of the patient, does not engage a side portion of the mouth and further does not engage a portion of the patient's face adjacent the side portion of the mouth.

14. The medical tube holder according to claim 13, further comprising a support bracket extending from said flange, said support bracket being axially aligned and spaced from said guard member and further being configured and arranged to support a medical tube.

5 15. The medical tube holder according to claim 14, further comprising a fastener dimensioned to secure the medical tube to said support bracket.

16. The medical tube holder according to claim 13, further comprising an attachment member supported by said upper portion of said flange, said attachment member being configured and
10 arranged to engage the patient's face, adjacent a first and a second cheekbone.

17. The medical tube holder according to claim 16, wherein said attachment member includes a strap.

15 18. The medical tube holder according to claim 17, further comprising at least one slot disposed through said upper portion, said slot being dimensioned to receive said strap.

19. The medical tube holder according to claim 13, further comprising adhesive for attaching said upper portion of said flange to the patient's face.

20 20. The medical tube holder according to claim 13, wherein said guard member includes a floor, a ceiling spaced from and opposed to said floor, a sidewall disposed between said floor and said ceiling and a longitudinally extending opening disposed opposite said side wall.

25 21. The medical tube holder according to claim 14, further comprising an intermediate bracket disposed between said guard member and said support bracket, said guard member including a top plate supported by said intermediate bracket.

22. A medical tube holder configured and arranged to be at least partially inserted into a mouth of a patient, comprising:

a flange having an upper portion engageable with an upper lip of the mouth along a central portion thereof;

5 an attachment member engageable with said upper portion of said flange, said attachment member being configured and arranged to engage the patient's face, adjacent a first and a second cheekbone; and

a guard member extending from said flange, said guard member configured and arranged for insertion within the mouth of the patient;

10 wherein said flange engages only an upper, central portion of the mouth of the patient such that access to the mouth along a first and a second side thereof is unobstructed when said guard member is inserted into the mouth of the patient.

23. The medical tube holder according to claim 22, wherein said attachment member includes
15 a strap.

24. The medical tube holder according to claim 23, further comprising at least one slot disposed through said upper portion, said slot being dimensioned to receive said strap.

20 25. The medical tube holder according to claim 22, wherein said flange includes a contoured upper portion configured and arranged to engage the patient's face, adjacent the first and second cheekbones, when said guard member is inserted in the mouth of the patient.

26. The medical tube holder according to claim 22, wherein said flange further comprises a
25 lower portion engageable with a lower lip of the mouth of the patient, along a central portion thereof.

27. A method for supporting a medical tube received within the mouth of a patient comprising:

providing a medical tube holder including a flange having an upper portion and a lower portion and a guard member extending from said flange;

5 inserting said guard member into the mouth of the patient and over the medical tube;
engaging an upper portion of the patient's lip with said upper portion of said flange;
engaging a lower portion of the patient's lip with said lower portion of said flange; and
securing said medical tube holder to the patient such that said holder does not contact a
side portion of the patient's mouth and further does not engage a portion of the patient's face
10 adjacent the side portion of the mouth.

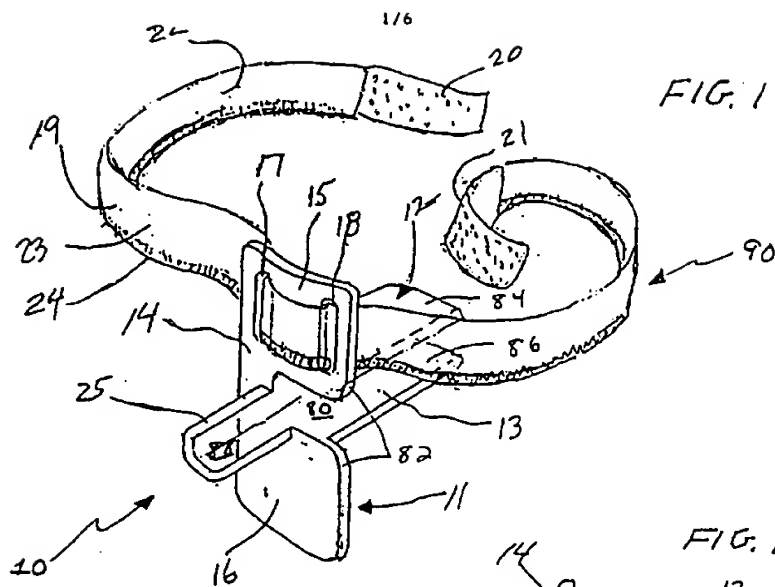


FIG. 1

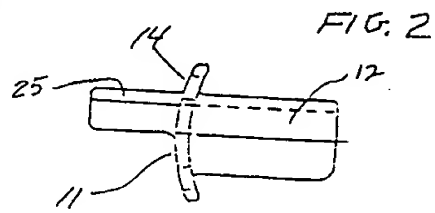


FIG. 2

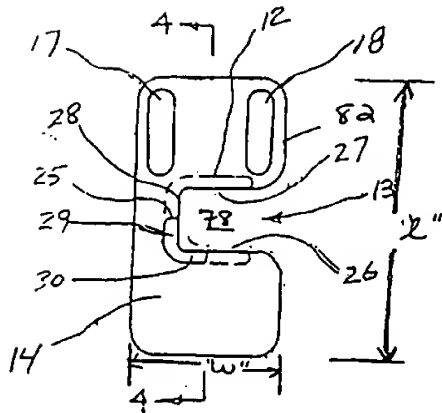


FIG. 3

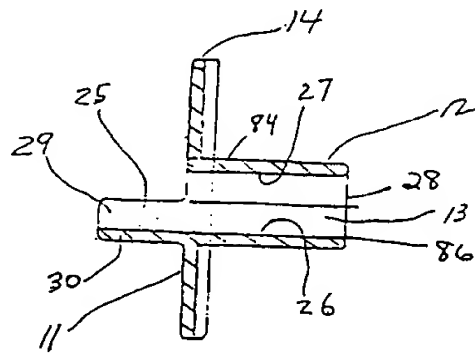
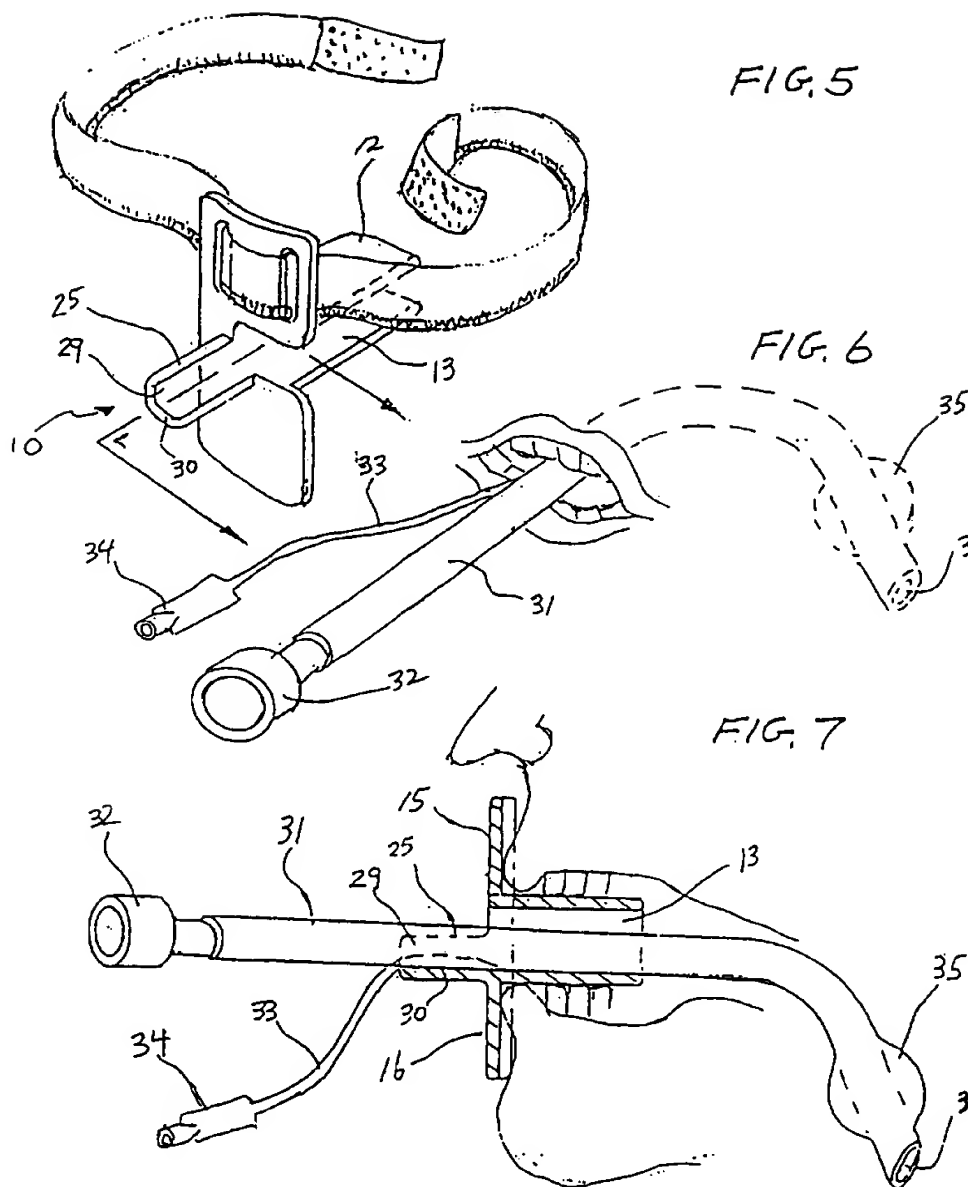
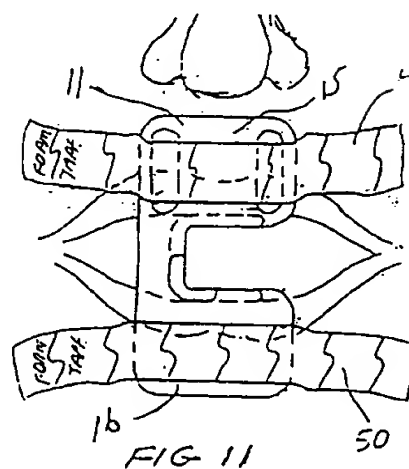
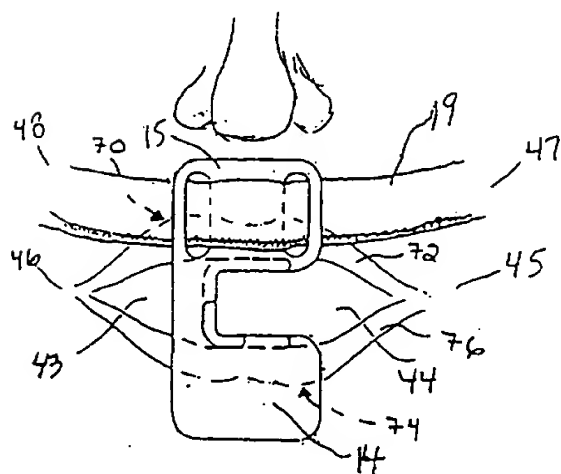
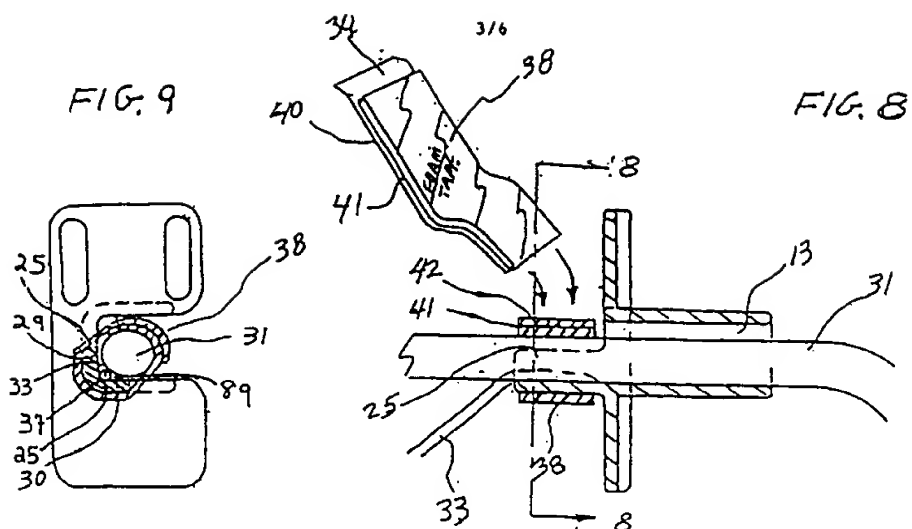


FIG. 4

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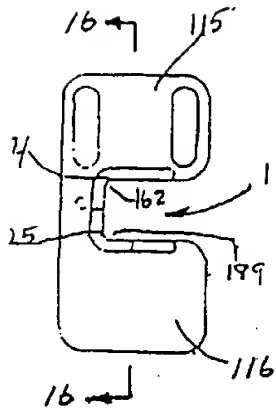
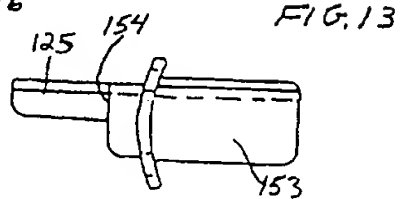
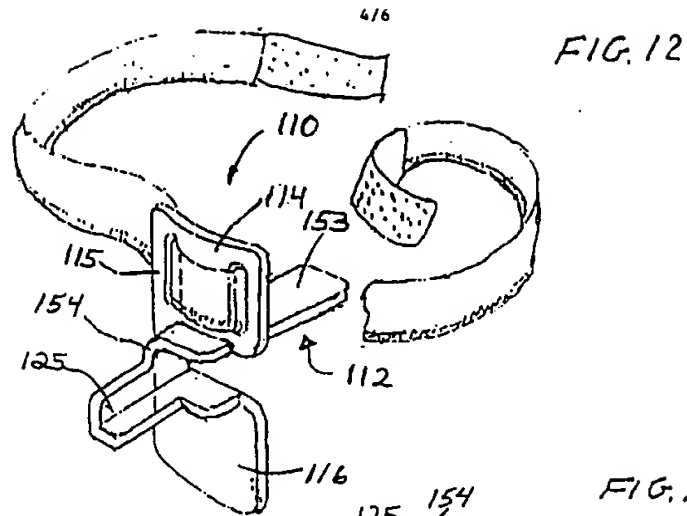


FIG. 14

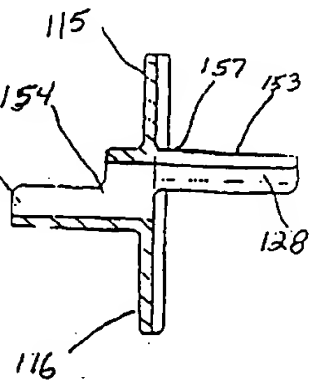


FIG. 15

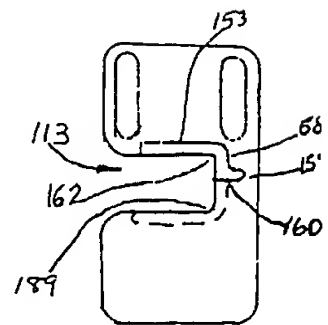


FIG. 16

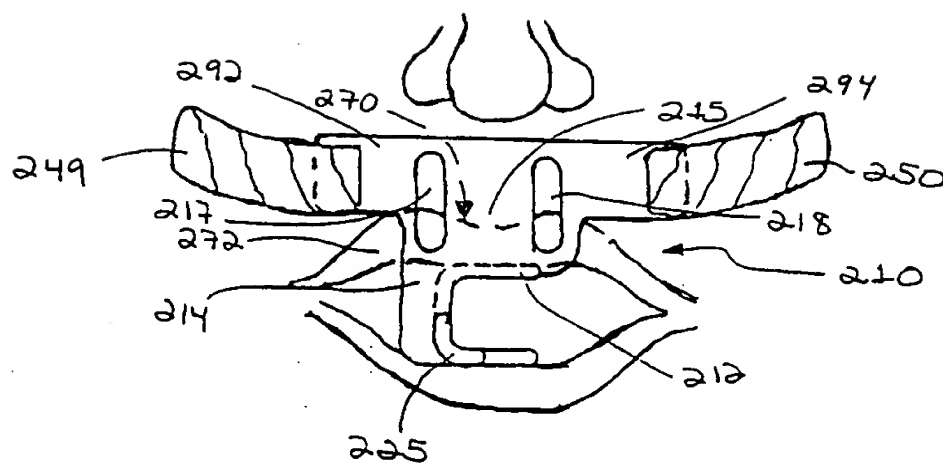
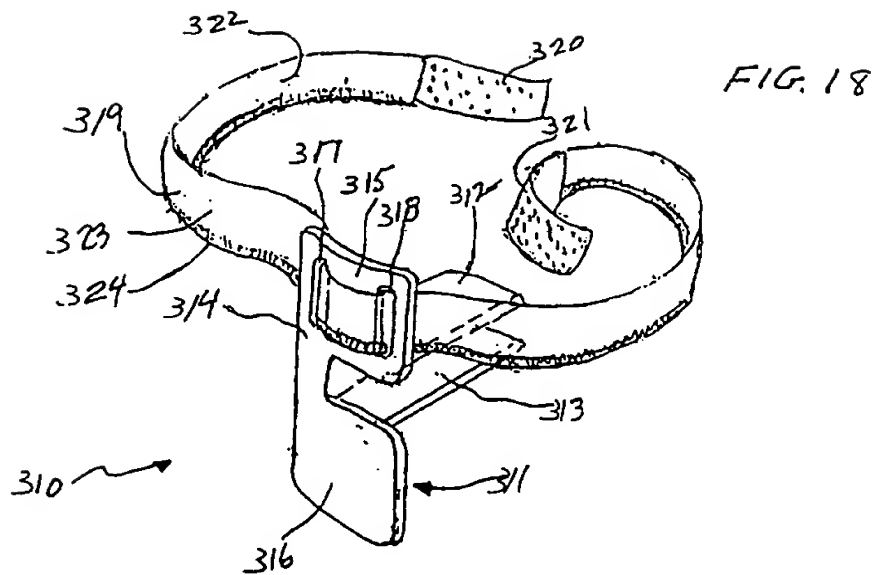


FIG. 17



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/10049

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 29727 A (ISLAVA STEVEN T) 9 November 1995	1-3,9, 11,12
Y	see abstract; figures see page 5, line 1 - page 7, line 10 ---	4-8,10, 13-26
Y	US 4 329 984 A (KERVIN DAVID) 18 May 1982 see abstract; figures see column 1, line 33 - column 2, line 6 ---	4
Y	US 4 351 331 A (GEREG GORDON A) 28 September 1982 see abstract; figure 7 see column 6, line 14 - line 66 ---	5-8, 13-26
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

10 October 1997

Date of mailing of the international search report

06.11.97

Name and mailing address of the ISA

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Authorized officer

Zeinstra, H

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/10049

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	<p>US 5 421 327 A (FLYNN MARY E ET AL) 6 June 1995 see abstract; figures 1,2 see column 2, line 3 - line 17 -----</p>	10

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 97/10049

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos. 27
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos. .
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically.
3. ☐ Claims Nos. .
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/10049

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9529727 A	09-11-95	US 5402776 A US 5513633 A AU 2357795 A CA 2188865 A EP 0757569 A	04-04-95 07-05-96 29-11-95 08-11-95 12-02-97
US 4329984 A	18-05-82	NONE	
US 4351331 A	28-09-82	NONE	
US 5421327 A	06-06-95	NONE	